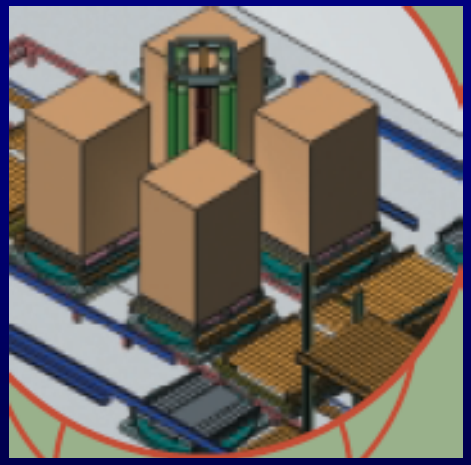
U.S.NRC

UNITED STATES NUCLEAR REGULATORY COMMISSION

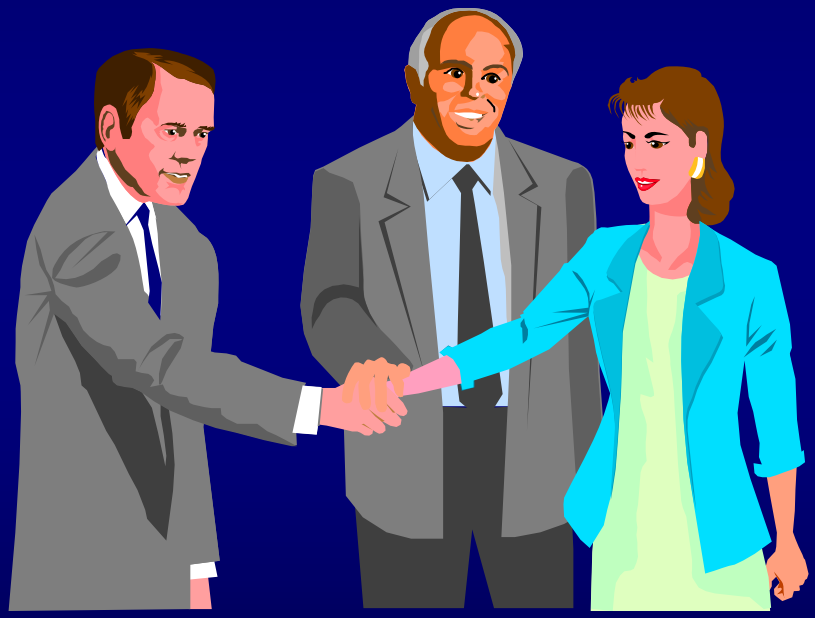
*Protecting People and the Environmentar*

HRTD Human Resources Training & Development

# 10 CFR Part 36
# Irradiator Licenses



# Topic Experience



- Experience in 10 CFR Part 36 Irradiator topics?

# 10 CFR Part 36

- Published in Federal Register on February 9, 1993
- Effective date – July 1, 1993
- Last revision published in Federal Register on October 6, 1997

# Definitions

# Irradiator

- Means a facility that uses radioactive sealed sources for the irradiation of objects or materials and in which radiation dose rates exceeding 5 grays (500 rads) per hour exist at 1 meter from the sealed radioactive sources in air or water, as applicable for the irradiator type, but does not include irradiators in which both the sealed source and the area subject to irradiation are contained within a device and are not accessible to personnel.

# Panoramic Dry-Source-Storage Irradiator

- Means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored in shields made of solid materials. The term includes beam-type dry-source-storage irradiators in which only a narrow beam of radiation is produced for performing irradiations.

# Panoramic Irradiator

- Means an irradiator in which the irradiations are done in air in areas potentially accessible to personnel. The term includes beam-type irradiators.

# Panoramic Wet-Source-Storage Irradiator

- Means an irradiator in which the irradiations occur in air in areas potentially accessible to personnel and in which the sources are stored under water in a storage pool.

# Pool Irradiator

- Means any irradiator at which the sources are stored or used in a pool of water including panoramic wet-source-storage irradiators and underwater irradiators.

# Underwater Irradiator

- Means an irradiator in which the sources always remain shielded under water and humans do not have access to the sealed sources or the space subject to irradiation without entering the pool.

# 10 CFR Part 36

- Regulatory requirements for panoramic (dry or wet storage), underwater, and irradiators whose dose rates exceed 5 grays (500 rads) per hour @ 1 meter licenses.

- Specific elements which the applicant must submit, as follows:

# Elements of an Application

- Training
- Operating and Emergency procedures
- Organizational structure (chart) and delegation of authority and responsibility
- Access control systems required by 10 CFR 36.23
  - Radiation monitors required by 10 CFR 36.29
  - Leak testing method required by 10 CFR 36.59
    - Leak test kit, method approved by NRC or Agreement State OR
    - "In-house" by applicant/licensee

# Elements of an Application

- Load or unloading sources:
  - Organization specifically authorized by the NRC or Agreement State; OR
  - "In-house" by applicant/licensee
- Inspection and maintenance checks required by 10 CFR 36.61

# 10 CFR Part 36 Divisions

- Subpart A - General Provisions
- Subpart B - Specific Licensing Requirements
- Subpart C - Design and Performance Requirements for Irradiators
- Subpart D - Operation of Irradiators
- Subpart E - Records
- Subpart F - Enforcement

Copies of 10 CFR Part 36 are available in the classroom.

# NUREG-1556 VOLUME 6

## PROGRAM-SPECIFIC GUIDANCE ABOUT 10 CFR PART 36 IRRADIATOR LICENSES

# Action Type

- New License
- Amendment to License
- Renewal to License

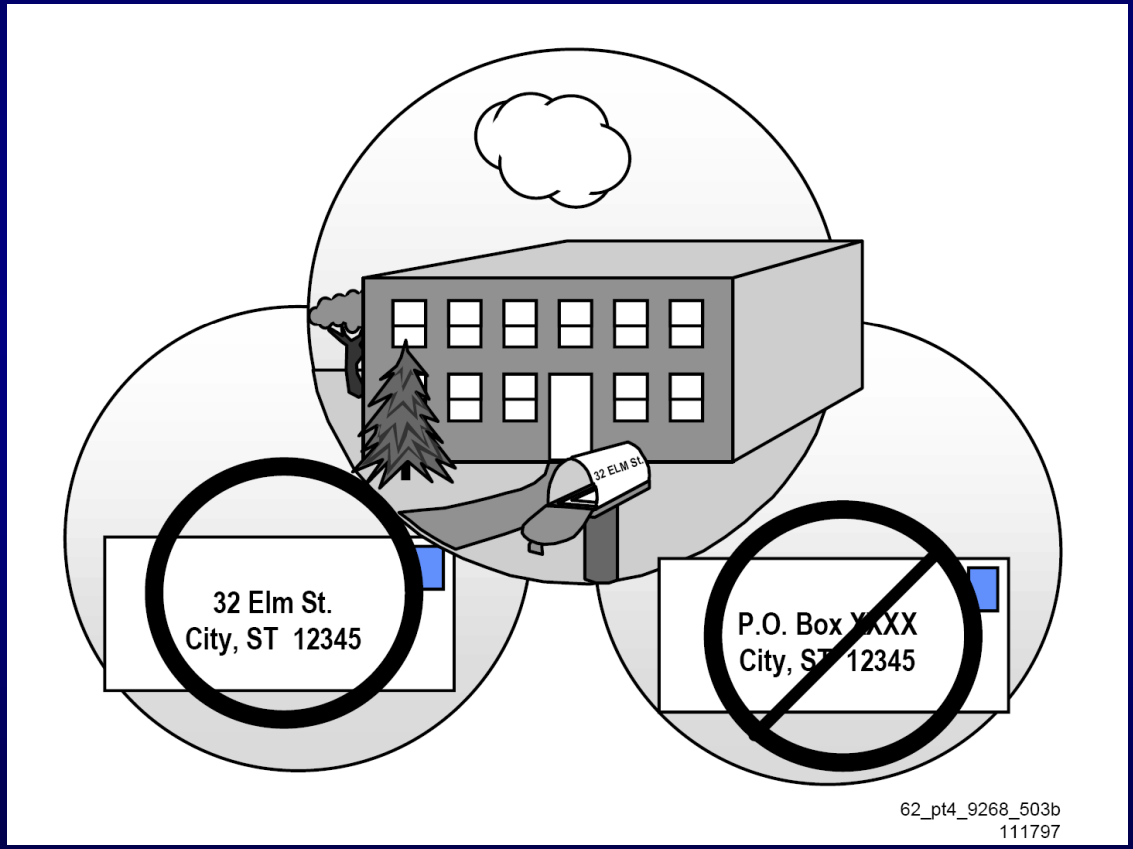
# Name and Mailing Address

- Legal Name of corporation or legal entity
- A division or department within a legal entity may <u>not</u> be a licensee
- Individual acting in private capacity
- Mailing address

# Transfer of Control

- 10 CFR 30.34(b)
- Mergers
- Contractual Agreements
- Buyouts
- Majority Stock Transfer
- NUREG 1556, Volume 15, Appendix F

# Location of Use



# Contact Person

- Individual who can answer questions about the application.
- Telephone number

# Sealed Sources & Devices - Irradiators

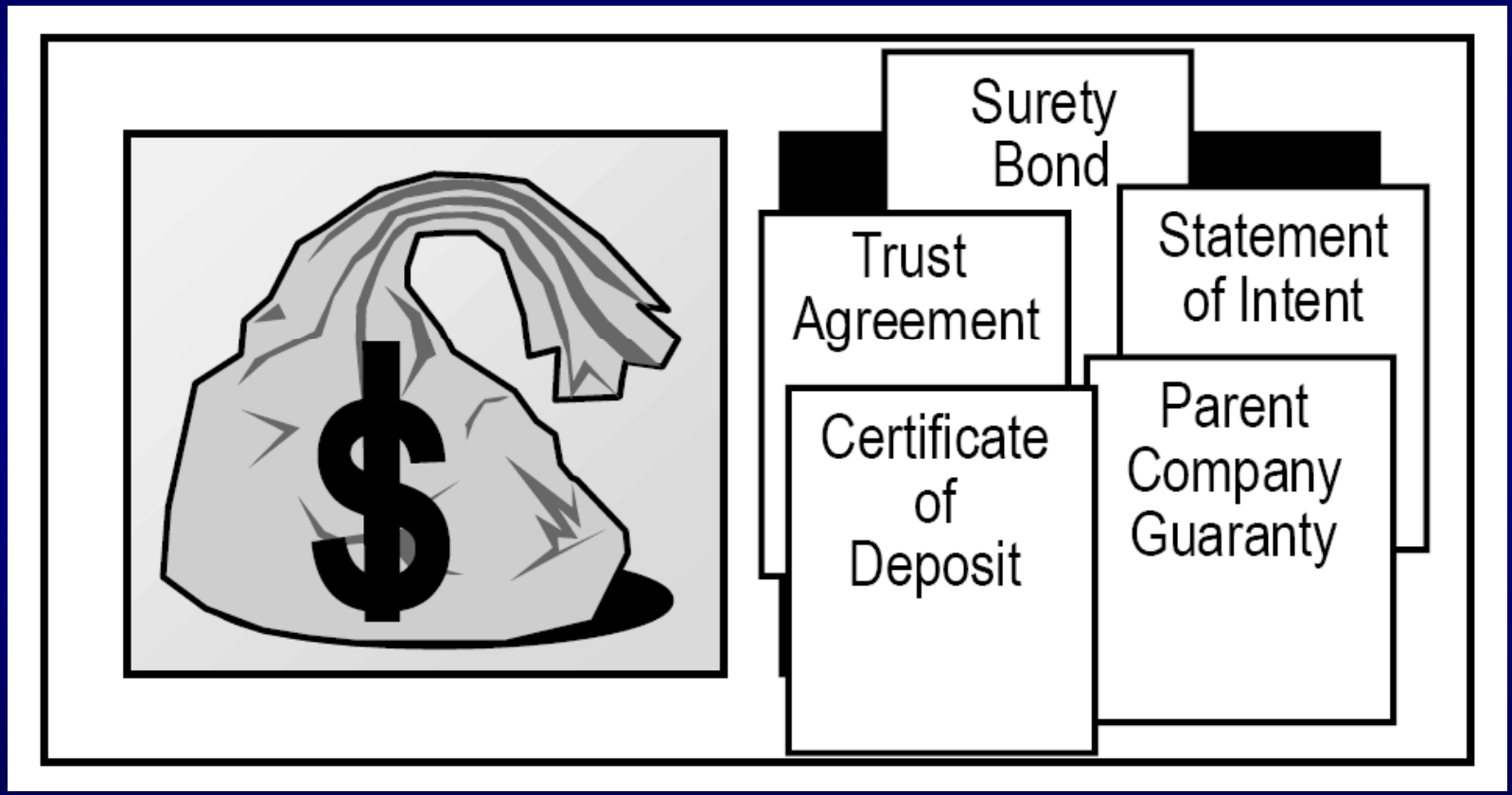
- Identify each radionuclide that will be used in each irradiator
- Identify the manufacturer (or distributor) and model number of each sealed source.
- Identify the manufacturer (or distributor) and model number of each irradiator, if applicable
- Specify the maximum activity per source (dry-source-storage irradiators)
- Specify the maximum activity per irradiator
- DU as shielding material, specify the total amount (in kg)

# Financial Assurance

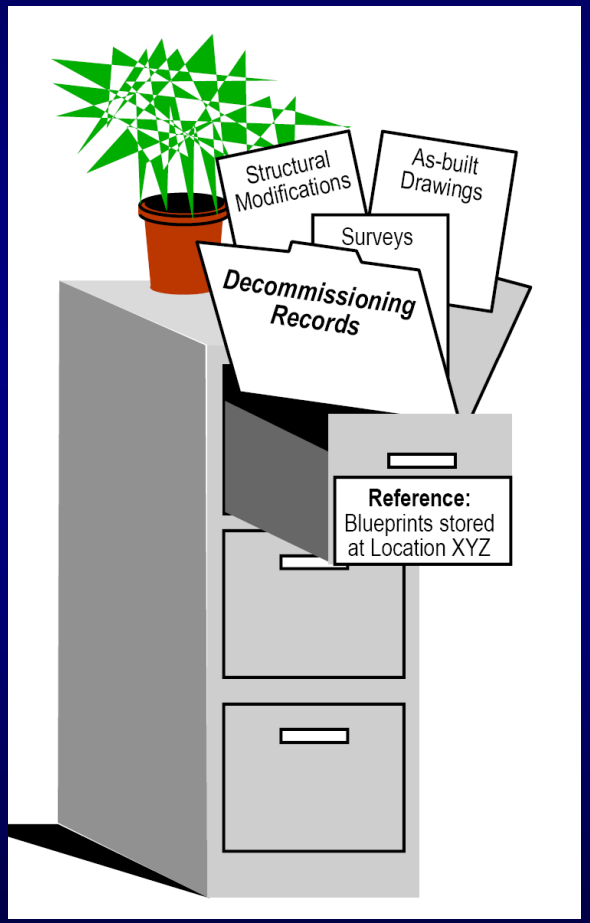
- Cobalt-60 - 10,000 Curies
- Cesium-137 - 100,000 Curies
- NUREG-1757, VOLUME 3, "Consolidated NMSS Decommissioning Guidance Financial Assurance, Record keeping, and Timeliness, dated September 2003:

Required amount - $113,000 (10 CFR 30.35(d))

# Financial Assurance Methods



# Decommissioning Records



# Recordkeeping Requirements for Decommissioning

- Identified location
- As-built drawings showing modifications to structures and equipment
- Sketch of rooms, buildings, or narrative description of the area
- Unusual occurrences (leaking source or other incidents that involve contamination)
- Does not apply to temporary jobsites

# Purpose for Which Licensed Material Will Be Used

- Requests to use sealed sources for purposes not listed in SSD - reviewed on a case-by-case basis
- Authorizations generally prohibited:
  - Greater than small quantities of flammable materials with flash point below 60°C
  - Irradiation of explosive material
  - Cryogenic material

# 10 CFR 51.22(c)(14)(vii)

- **Normally categorically excluded; therefore, environmental assessment not required**

# Radiation Safety Officer
# Irradiator

- An individual with responsibility for the overall radiation safety program at the facility

# Radiation Safety Officer Qualifications

- No previous formal training in health physics nor certification by the American Board of Health Physics:
  - 40 hours covering the following:
    - Radioactivity and radioactive decay
    - Interactions of radiation with matter
    - Biological effects of radiation
    - Radiation detection using radiation detection instruments and personnel dosimeters
    - Basic radiation protection principles and good safety practices (including time, distance, and shielding)
    - Radiation protection regulations

# Radiation Safety Officer Qualifications

- Previous RSO experience but no irradiator work experience:
  - 40 hours general radiation topics
  - 40 hours self-study or directed study on information directly applicable to radiation safety at irradiators
    - Applicable regulations (10 CFR Parts 20 and 36)
    - Reports or studies describing case histories of accidents or problems at irradiators

# Radiation Safety Officer Qualifications

- Experienced RSO:
  - Course content:
    - Radiation safety
    - Regulatory requirements
    - Practical explanation of the theory and operation for irradiators
  - Requirements of 10 CFR Parts 19, 20, and 36 relevant to the irradiator
  - Operating and Emergency procedures listed in 10 CFR 36.53
  - Case histories of accidents or problems involving irradiators

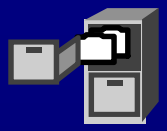
# Radiation Safety Officer Effectiveness

- Sufficient time & commitment from management
- Describe the organizational structure for managing the irradiator
  - RSO should report directly to the facility manager
  - Describe who has the authority to stop unsafe operations
  - Named individual knows of his/her designation as RSO

# RSO Duties & Responsibilities

Stopping Unsafe Licensed Activities

Proper Use and Routine Maintenance

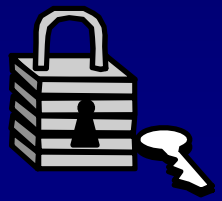


Records Maintenance

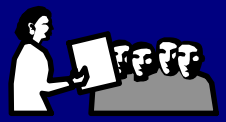
Annual Program Audit

Maintenance – Inspection Checks

Monitor Emergency Events



Security of Licensed Material



Personnel Training

Interaction with NRC, Other Authorities

Material Disposal

Investigation of Abnormal Events

# Irradiator Operator

**An individual who has successfully completed the training and testing described in 10 CFR 36.51 and is authorized by the terms of the license to operate the irradiator without a supervisor present**

# Initial Training & Experience for Irradiator Operators - Appendix G

- Ensure training in 10 CFR 36.51(a) topics
- On-the-Job Training
  - Supervised hands-on experience performing:
    - Operating procedures
    - Test runs of emergency procedures
    - Routine maintenance
    - Lock-out procedures
  - 3 months (full time equivalent)

# Appendix G

- Written Examination
  - 25 to 50 questions
  - Closed Book
  - 70% Minimum Passing Grade
- Annual safety review:
  - Changes in Operating and Emergency procedures since last review
  - Changes in regulations and license conditions since the last review
  - Reports on recent accidents, mistakes, or problems that have occurred at irradiators

# Appendix G

- Annual safety review:
  - Relevant results of inspections of operator safety performance
  - Relevant results of the facility's inspection and maintenance checks
  - Drill to practice an emergency or abnormal event procedure

- Annual safety performance of each irradiator operator:
  - Applicable regulations
  - License conditions
  - Operating and Emergency procedures

# Training for Individuals Requiring Unescorted Access

- Instructed and tested in:
  - Precautions to avoid radiation exposure
  - Procedures listed in 10 CFR 36.53 to be performed or complied with
  - Proper response to alarms
- Tests may be oral
- No response is required during the licensing phase

# Facilities & Equipment

- Drawings, diagrams, sketches, photographs and description of the irradiator
- On these drawings, diagrams, sketches, and photographs, show locations of safety-related equipment and features as required in 10 CFR Part 36
- Provide a construction schedule for the irradiator

# Access Control
# Panoramic Irradiators

- Necessary to prevent inadvertent entry into the radiation room
- Describe the access control system and how it works that demonstrates compliance with the requirements of 10 CFR 36.23
  - Specific drawings or sketches should be submitted, as appropriate.

# Access Control
# Panoramic Irradiators

- Describe facility alarm systems
- Describe the lock and key system for controlling source movement
  - Meet requirements of 10 CFR 36.31(a)

# Access Control
# Underwater Irradiators

- Personnel access barrier with an intrusion alarm
- Only operators and facility management may have access to keys to the personnel access barrier
- Intrusion alarm able to detect unauthorized entry when the personnel access barrier is locked
- Activation of intrusion alarm must alert an individual prepared to respond or summon assistance

# Shielding

- Panoramic irradiators:
  - Describe the shielding to be used and its composition
  - Submit a diagram showing shielding configuration including walls and the ceiling
    - Indicate the thickness of each and penetrations in the shielding

# Shielding

- Panoramic irradiators:
  - Accessible areas outside shield expected to have dose rate exceeding 0.02 mSv (2 mrem) per hour:
    - Identify areas
    - Explain how access will be controlled
  - Requests to possess more than 5 million Curies:
    - Submit an evaluation of the effects of heating of the shielding walls by the irradiator sources

# Shielding

- Panoramic irradiator construction:
  - Identify building code requirements to which shielding walls will be built
  - Identify inspections of the construction to be performed by local authorities.
- Underwater irradiators:
  - No response is required during the licensing phase

# Fire Protection

- Panoramic irradiators, describe:
  - Type and location of the heat and smoke detectors to be used to detect a fire in the radiation room.
  - Alarms to alert personnel trained to summon assistance.
  - How the sources will automatically become fully shielded if a fire is detected.
  - How the heat and smoke detectors will be tested.

- Underwater irradiators:
  - No response is required during the licensing phase

# Fire Protection

- Panoramic irradiators construction:
  - Verify the number, location and spacing of the smoke and heat detectors are appropriate to detect fires and that the detectors are protected from mechanical and radiation damage
  - Verify that the design of the fire extinguishing system provides the necessary discharge patterns, densities, and low characteristics for complete coverage of the radiation room and the system is protected from mechanical and radiation damage

# Fire Protection

- Panoramic irradiators construction:
  - Test the ability of the heat and smoke detectors to detect a fire, to activate alarms, and to cause the source rack to automatically become fully shielded
  - Test the operability of the fire extinguishing system

# Radiation Monitors

- Describe the location and type of radiation monitors used to meet the requirements of 10 CFR 36.23(c), 36.29, and 36.59(b)
- Describe the location and types of alarms in addition to those individuals who are trained to respond to those alarms
- Discuss alarm set-points or methods for establishing the alarm set-points
- For irradiator construction, describe the evaluation performed to meet 10 CFR 36.39(e) on detector location and sensitivity and the acceptance testing performed to meet 10 CFR 36.41(e)

# Irradiator Pools

- For all pool irradiators, describe:
  - High and low water-level indicators and their locations
  - Purification system for the pool with an explanation of why it is capable of maintaining pool water conductivity less than 20 microsiemens per centimeter
  - Means to replenish pool water
  - Barrier used during normal operation to prevent personnel from falling into the pool

# Irradiator Pools

- For all pool irradiators, describe:
  - How high radiation doses from radiation streaming will be avoided when using long-handled tools or poles
  - The means of preventing inadvertent excessive loss of pool water, if pool has outlets more than 0.5 meter below the surface that could allow water to drain out of the pool
  - The pool liner

# Source Rack

- Submit procedures for ensuring source rack protection
- If product moves on a conveyer system, describe the source rack protection provided to prevent products and product carriers from touching the source rack or mechanism that moves the rack

# Source Rack

- For panoramic irradiators, test the movement of the source racks for proper operation prior to source loading
- For all irradiators with product conveyor systems, the applicant/licensee must observe and test the operation of the conveyor system to ensure that the requirements in 10 CFR 36.35 are met

# Power Failures

- Panoramic irradiators:
  - Describe how the sources are automatically returned to the shielded position if offsite power is lost for longer than 10 seconds
  - Describe how loss of power will affect the lock on the doors in the radiation room
- Underwater irradiators:
  - No response is required during the licensing phase

# Annual Radiation Safety Audit

- 10 CFR 20.1101(c)
- The licensee shall periodically (at least every 12 months) ensure the following:
  - Compliance with NRC and DOT regulations
  - Terms and conditions of the license
  - Occupational doses and doses to members of the public ALARA
  - Records of audits and other reviews of program content maintained for 3 years
- Guidance may be found in Appendix K of NUREG-1556, Volume 6
- No response is required during the licensing phase

# Instruments

- Survey instruments:
  - Measure the type of radiation expected
  - Do not saturate and read zero at high radiation dose rates
  - Calibrated:
    - At least every 12 months
    - Using a source of radiation similar to that found in the irradiator
    - After any servicing or repair

# Instruments

- Survey instruments:
  - Calibrated:
    - Ensure that exposure rates indicated by the meter do not vary from the actual exposure rates by more than ± 20% on each scale
    - By the instrument manufacturer or person specifically authorized by the NRC or an Agreement State to calibrate survey instruments - OR

# Instruments

- Survey instruments:
  - Calibrated:
    - In-house calibration in accordance with Appendix L or describe alternative procedures
  - Measure at least 0.05 mR - 200 mR per hour
    - Checked for functionality with check source at beginning of each day of use

# Instruments

(See NUREG 1556 Volume 6 page 8-35 for full size table)

**Table 8.2 Requirements for Radiation Monitors**

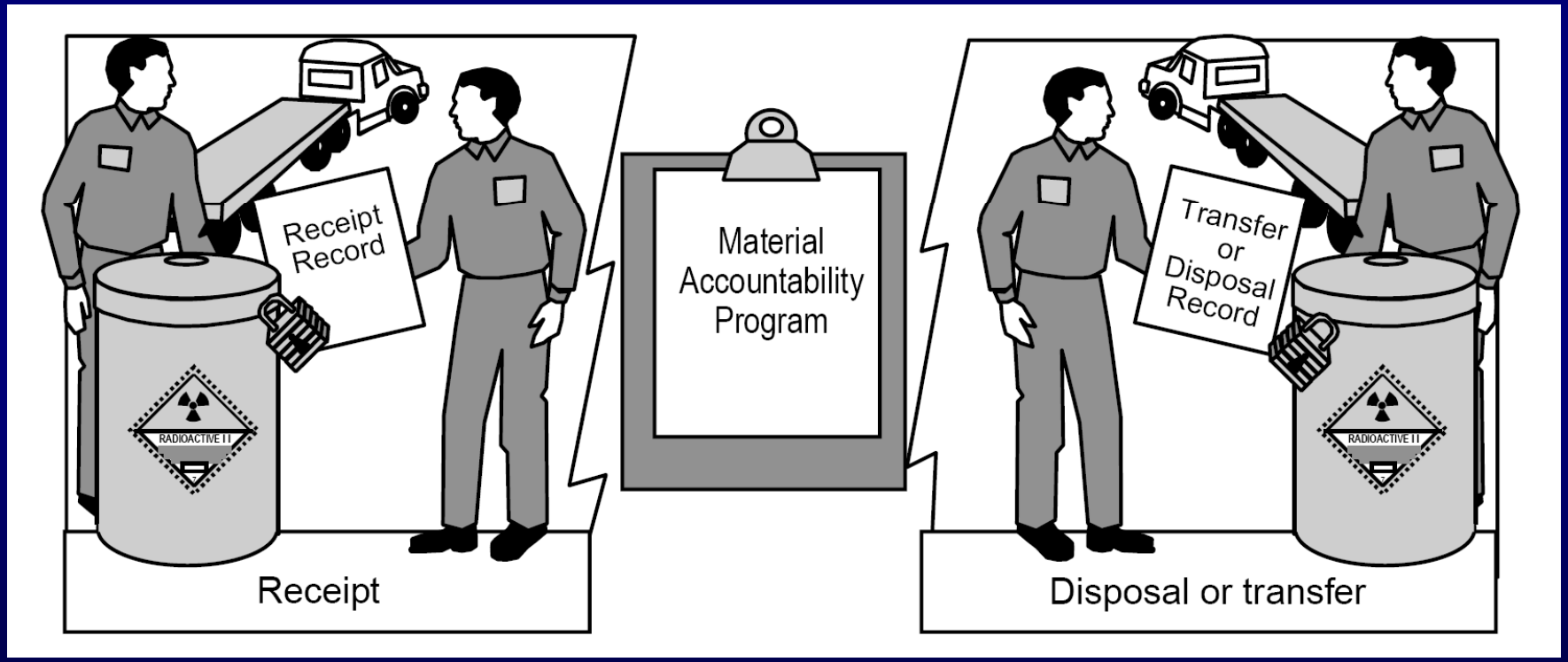
| Type of Irradiator | Monitor Required | Purpose of Monitor | Required Checks |
|---|---|---|---|
| Panoramic pool | Gamma sensing integrated with personnel access locks. Must activate alarm if entry is attempted while sensing radiation. 10 CFR 36.23(c) | Detects presence of high radiation in radiation room to prevent room access when rad levels are high | Periodic checks with radioactive check source to confirm operability |
| All pool types (required unless water is checked daily by analysis of a sample of pool water) | Gamma sensing of pool circulating system. Must activate an alarm set-point as low as practical when pool is contaminated. 10 CFR 36.59(b) | Detects a possible leaking sealed source | Periodic checks with radioactive check source to confirm operability and sensitivity |
| Underwater type not in a shielded radiation room | Gamma sensing mounted over the pool. Must have an audible alarm capable of alerting an authorized individual. 10 CFR 36.29(b) | Detects abnormal radiation levels | Periodic checks with radioactive check source to confirm operability and sensitivity |
| Any irradiator using a product conveyor system | Gamma sensing to detect and stop the product conveyor if a source is present. 10 CFR 36.29(a) 10 CFR 36.39(e) | Must stop conveyor before a source on the conveyor can cause a radiation overexposure to any person. | Periodic checks with radioactive check source to confirm operability. The location and sensitivity of the monitor to detect sources carried by the product conveyor must be evaluated. |

# Instruments

- Radiation monitors:
  - Detect the presence of radiation for various purposes at irradiator facilities
  - Vital to access control systems
  - Designed to provide fail-safe operation

# Material Receipt and Accountability

## "Cradle" to "Grave" Accountability



# Material Receipt and Accountability

- Accountability Procedures:
  - Pool irradiator
    - No lost sources when sources are added to, removed from or moved within the irradiator
    - Records maintenance that include sealed source serial numbers and location of each source
  - Panoramic dry-source-storage irradiator
    - Leak tests
    - No lost sources when sources are added to, removed from or moved within the irradiator
    - Records maintenance that include sealed source serial numbers and location of each source

# Material Receipt and Accountability

- Receipt, transfer, and disposal records:
  - Receipt record
    - Maintained for as long as the material is possessed until 3 years after transfer or disposal
  - Transfer record
    - Maintained for 3 years after transfer
  - Disposal record
    - Maintained until NRC terminates the license

# Material Receipt and Accountability

- Receipt, transfer, and disposal records:
  - Records contain the following types of information:
    - Radionuclide, activity (in units of bqs or Cis), date of measurement of byproduct material in each sealed source
    - Manufacturer's (or distributor's) name, model number, and serial number of each sealed source containing byproduct material
    - Location of each sealed source

# Material Receipt and Accountability

- Receipt, transfer, and disposal records:
  - Records contain the following types of information:
    - Materials transferred or disposed of, the date of transfer or disposal, name and license number of recipient, description of the affected radioactive material
      - radionuclide
      - activity
      - manufacturer's (or distributor's) name and model number
      - serial number

# Occupational Dosimetry

- Film badge
- TLD
- OSL
- Pocket dosimeters (for other individuals or anyone who could receive in 1 yr a radiation dose in excess of 10% of the allowable limits)
- NVLAP - Approved
- Exchange Frequency
- No response is required during the licensing phase

# Public Dose

- 10 CFR 20.1301
- Ensure that irradiators and their sealed sources will be used, transported, and stored in such a way that members of the public will not receive more than 100 mrem in any one year, and the dose in any unrestricted area will not exceed 2 mrem in any one hour

# Public Dose

- Control and maintain constant surveillance over licensed material not in storage
- Secure stored licensed material from unauthorized access, removal, or use
  - Control and interlock systems should be locked and secured against unauthorized access

# Public Dose

- Examples of methods to demonstrate compliance may be found in Appendix N of NUREG-1556, Volume 6
- No response is required during the licensing phase

# Operating Procedures

- Elements must include items specified in 10 CFR 36.53(a):
  - Operation of the irradiator, including entering and leaving the radiation room
  - Use of personnel dosimeters
  - Surveying the shielding of panoramic irradiators
  - Monitoring pool water for contamination while the water is in the pool and before release of pool water to unrestricted areas

# Operating Procedures

- Elements must include items specified in 10 CFR 36.53(a):
  - Leak testing of sources
  - Inspection and maintenance checks required by 10 CFR 36.61
  - Loading, unloading, and repositioning sources (if performed by the licensee)
  - Inspection of movable shielding required by 10 CFR 36.23(h), if applicable

# Repair and Preventive Maintenance

- Maintenance, service, and repair procedures performed according to the manufacturer's written instructions.
  - Outlines of the above procedures not required.
- Malfunctions and defects found during inspection and maintenance checks must be repaired without undue delay
- Preventive maintenance performed according to the manufacturer's written instructions

# Operating Procedures Revision

- May revise Operating procedures w/o NRC approval only if:
  - Revisions do not reduce the safety of the facility
  - Revisions are consistent with the outline or summary of procedures submitted with the license application
  - Revisions have been reviewed and approved by the RSO
  - Users or operators are instructed and tested on the revised procedures before they are put into use.

# Reporting Defects and Non-Compliance

- Procedure for Identifying and Reporting Defects and Non-Compliance Required by10 CFR Part 21
  - If defects and failures are found in a basic component that could create a substantial safety hazard, must notify NRC.
  - No response is required during the licensing phase

# Emergency Procedures

- Emergency and abnormal event procedures for the following:
  - Sources stuck in the unshielded position
  - Personnel overexposures
  - Radiation alarm from the product exit portal monitor or pool monitor
  - Detection of leaking sources, pool contamination, or alarm caused by contamination of pool water
  - Low- or high-water level indicator, an abnormal water loss, or leakage from the source storage pool

# Emergency Procedures

- Emergency and abnormal event procedures for the following:
  - Prolonged loss of electrical power
  - Fire alarm or explosion in the radiation room
  - Alarm indicating unauthorized entry into the radiation room, area around pool, or another alarmed area
  - Natural phenomena, including an earthquake, a tornado, flooding, or other phenomena as appropriate for the geographical location of the facility
  - Jamming of automatic conveyor systems

# Emergency Procedures

- Emergency and abnormal event procedures should include the following:
  - Person to be notified of event
  - Role of the RSO
  - Records kept of event

# Emergency Procedures

- Emergency and abnormal event procedures should include the following:
  - Actions to be taken immediately after discovering the emergency or abnormal event
  - Notification of NRC upon events specified in Appendix O
- Copies of Emergency procedures provided to all irradiator operators.
- Current copies of Emergency procedures posted at each site

# Emergency Procedures Revision

- May revise Emergency procedures w/o NRC approval only if:
  - Revisions do not reduce the safety of the facility
  - Revisions are consistent with the outline or summary of procedures submitted with the license application
  - Revisions have been reviewed and approved by the RSO
  - Users or operators are instructed and tested on the revised procedures before they are put into use

# Leak Test

- Dry-source-storage irradiators:
  - Leak tests performed at intervals not to exceed 6 months
  - Performed by organization authorized by NRC or Agreement State to perform this service OR
  - Use of leak test kit provided by an organization licensed by NRC or an Agreement State OR
  - In house by applicant using procedures in Appendix P or describe alternatives OR

# Leak Test

- Dry-source-storage irradiators:
  - Description of alternative equipment and/or procedures for determining whether there is any radioactive leakage from sources contained in the irradiator
  - Authorized by License Condition

# Leak Test

- Pool irradiators:
  - Description of equipment, procedures, and sensitivity of method that will be used to check for contamination by analysis of a sample of pool water OR
  - Description of equipment, procedures, and sensitivity of method that will be used to check for contamination by continuous monitoring

# Inspection and Maintenance Checks

- Inspection & maintenance checks for the following items:
  - Operability of each aspect of the access control system required by 10 CFR 36.23
  - Functioning of the source position indicator as required by 10 CFR 36.31(b)
  - Operability of the radiation monitor for radioactive contamination in pool water required by 10 CFR 36.59(b)
  - Operability of the over-pool radiation monitor at underwater irradiators as required by 10 CFR 36.29(b)

# Inspection and Maintenance Checks

- Inspection & maintenance checks for the following items:
  - Operability of the product exit monitor required by 10 CFR 36.29(a)
  - Operability of the emergency source return control required by 10 CFR 36.31(c)
  - Leak-tightness of systems through which pool water circulates (visual inspection)
  - Operability of the heat and smoke detectors and extinguisher system required by 10 CFR 36.27 (w/o turning extinguishers on)

# Inspection and Maintenance Checks

- Inspection & maintenance checks for the following items:
  - Operability of the means of pool water replenishment required by 10 CFR 36.33(c)
  - Operability of the indicators of high and low pool-water levels required by 10 CFR 36.33(d)
  - Operability of the intrusion alarm required by 10 CFR 36.23(i), if applicable
  - Functioning and wear of the system mechanisms, and cables used to raise and lower sources

# Inspection and Maintenance Checks

- Inspection & maintenance checks for the following items:
  - Condition of the barrier to prevent products from hitting the sources or source mechanism as required by 10 CFR 36.35
  - Amount of water added to the pool to determine whether the pool is leaking
  - Electrical wiring on required safety systems for radiation damage
  - Pool water conductivity measurements as required by 10 CFR 36.63
  - Other necessary checks as appropriate (e.g., manufacturer's recommendations)
- Specify frequency of checks in the application

# Transportation

- Compliance with NRC and DOT regulations
- Transporting licensed materials originating at irradiator facilities require Type B package
  - Transfer possession to irradiator manufacturer who then acts as shipper
    - The manufacturer responsible for proper packaging of the radioactive materials and compliance with NRC and DOT regulations
- No response is required during the licensing phase

# Transportation

- Ensure that manufacturer:
  - Is authorized to possess the licensed material at temporary job sites
  - Actually takes possession of the licensed material under its license
  - Uses an approved Type B package
  - Is registered with NRC as a user of the Type B package
  - Has an NRC-approved QA plan

# Transportation

- Licensee as shipper in its own Type B packages:
  - Registered user of the Type B package
  - Has an NRC-approved QA plan
- No response is required during the licensing phase

# Minimization of Contamination

- No response is required during the licensing phase under certain conditions

# Orders

- Issued June 2003
- Implemented 180 days later
- Orders are Safeguards Information - Modified (SGI-M)
  - http://www.nrc.gov/reading-rm/doc-collections/enforcement/security/irradiators%20orders.pdf (non-SGM-M information)
- All 10 CFR Part 36 licensees received the orders.
- Must attend NRC Security Systems and Principles Training to inspect the licensees who received Orders.

# Waste Management

- Transfer to an authorized recipient
- Appropriate records must be maintained
- No response is required during the licensing phase; however, licensee should establish and include waste disposal procedures in its radiation safety program

# THE END